

## Intended Use

The Pointe Transferrin Control Set is intended to be used as a consistent test sample of known concentration for monitoring the performance of the Pointe Transferrin immunoturbidimetric assay. For in vitro diagnostic use only.

## Summary

The controls in this set are human serum, tested and found negative for HBsAg and antibodies to HCV and HIV. They contain known quantities of the listed constituents. They are to be used as controls with the Pointe Transferrin assay.

## Set Composition

Level 1 Human Serum (Liquid) 2 x 2mL  
Level 2 Human Serum (Liquid) 2 x 2mL

Pointe Transferrin Control, Level 1 and 2, contain pooled human serum with assigned values for transferrin.

## Warnings and Precautions

For In Vitro Diagnostic Use Only. Rx Only.

Not to be used internally in humans or animals. Normal precautions in handling laboratory reagents should be followed.

Controls contain pooled human serum. The serum has been tested and found non-reactive for the presence of HBsAg and antibody to HCV and HIV by an FDA accepted method. However, it is not possible to guarantee that any human source material is free of these infectious agents.

Therefore, all products containing human serum should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

Do not mix or use controls from one test set with those from a different lot.

Do not use controls past their expiration date stated on each control container label.

Controls in this set contain <0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of controls through plumbing fixtures, flush with copious amounts of water. For further information, refer to "Decontamination of Laboratory Sink Drains to remove Azide Salts," in the Manual Guide Safety Management No. CDC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

Do not pipette by mouth. Avoid ingestion and contact with skin.

## Control Preparation

Controls are liquid and ready to use.

## Storage and Handling Stability

Store controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls can be used for up to 18 months from the date of manufacture, as indicated by the expiration date on the package and bottle.

## Control Stability

Opened controls can be used for 1 month if stored at 2-8°C. Discard controls if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

## Procedure

### Materials Supplied

Level 1 Human serum 2 x 2 mL  
Level 2 Human serum 2 x 2 mL

### Materials Required But Not Supplied

Pointe Transferrin Immunoturbidimetric Assay Kits (T7535)  
Pointe Transferrin Calibrator (T7535-CAL)

Two-reagent clinical chemistry autoanalyzer capable of accurate absorbance reading at 340 and 700 nm, accurately dispensing the required volumes, and maintaining 37°C.

### Assay Procedure

Note: Allow all reagents and specimens to come to room temperature. Controls are liquid and ready to use. Mix all reagents gently before using.

The Pointe Transferrin Control Set is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the Pointe Transferrin Reagent Set.

### Limitations of Procedure

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. Erroneous results can occur from improper storage and technical errors associated with assay procedures.

This product is intended for use as an assayed control for the quantitative assay listed in the table below. This product is not intended for use as a calibrator.

### Expected Results

The manufacturer has established the expected values. Values listed were obtained using an Abbott Architect c8000 with Pointe Transferrin Reagent and Calibrators. Subsequent modifications in instrument, reagent, or procedure may invalidate these results. The assignment of mean values was derived from analysis of vials representative of the entire lot.

Values listed are specific for each lot only. Verify that the lot numbers on the vials of Transferrin Control correspond to the lot numbers listed for the assayed data.

The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation. It is considered good laboratory practice for each laboratory to establish its own mean and standard deviation for its test methods. The indicated Mean and Expected Range of the Mean should serve as a guide in assessing the performance of each test method.






**Control Values** Lot 331303 Exp. 2025-04-30



Analyte	Level 1	Level 2
Transferrin (mg/dL)*	196 ± 39	467 ± 47



\*Values are standardized to the CAP/BCR/IFCC Reference Prep. for Proteins in Human Serum (RPPHS), lot 91/0619

The expected values for the Pointe Transferrin Control Set are continually being revised through ongoing quality assurance. As a result, the expected values may change from lot to lot. Please refer to the package insert for each lot for the appropriate control values.

## Symbol Key

 Use by (YYYY-MM-DD)	<b>LOT</b> Lot and batch code
<b>REF</b> Catalog number	 Manufacturer
<b>IVD</b> <i>In vitro</i> diagnostic medical device	 Temperature limitation
 Consult instructions for use	<b>Rx Only:</b> Prescription Use Only
 CE mark	<b>EC REP</b> Authorized representative in the European Community

**REF** T7535-CTL Manufactured for HORIBA Instruments Incorporated  
- Pointe Brand  
5449 Research Drive Canton, MI 48188   2°C-8°C **IVD**

	Manufactured by Kamiya Biomedical Company 12779 Gateway Drive, Seattle, WA 98168 USA
<b>EC REP</b>	Advena Ltd. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta
	

## Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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